

**REMARKS**

Claims 1-15 and 19-23 are pending in this application. By the Office Action, claims 16-18 are withdrawn from consideration; claims 1-3, 10 and 11 are rejected under 35 U.S.C. §102(b); claims 1-5 and 9-15 are rejected under 35 U.S.C. §103(a); and claims 6-8 are objected to. By this Amendment, claims 16-18 are canceled; claims 1, 4 and 13 are amended for clarification purposes only; and claims 19-23 are added. Support for new claims 19-23 can be found in the specification at, for example, paragraphs [0037]-[0038]. No new matter is added.

I. Allowable Subject Matter

Applicants thank the Examiner for the indication that claims 6-8 are objected to as being dependent upon a rejected base claim, but are otherwise allowable. For all of the reasons set forth below, all of the pending claims are in condition for allowance.

II. Information Disclosure Statement

An Information Disclosure Statement with Form PTO-1449 was filed on April 25, 2002. On the copy of the Form PTO-1449 returned with the Office Action, three Japanese language references had been crossed out, indicating that they had not been considered of record, but without any explanation for such action.

Applicants respectfully submit that the non-consideration of the references was improper. Applicants submitted the references in accordance with their duty of disclosure under 37 C.F.R. §1.56 and §1.97. According to 37 C.F.R. §1.98, the Information Disclosure Statement must contain "a concise explanation of the relevance" of each non-English language document. That concise statement of relevance "can be either separate from the specification or

incorporated therein." 37 C.F.R. §1.98(a)(3). Applicants are in no way required to obtain and provide English language translations of any non-English language documents.

Applicants fully satisfied these duties, and therefore the references must be considered. In particular, the Information Disclosure Statement clearly indicated that English-language abstracts of the references were provided. The Examiner is respectfully requested to consider the disclosed information, and initial and return to Applicants a copy of the Form PTO-1449 indicating that the references have been considered of record. For the Examiner's convenience, attached hereto is a copy of the Form PTO-1449.

### III. Restriction Requirement

Claims 16-18 are withdrawn from consideration. Although Applicants do not necessarily agree with the Restriction Requirement, non-elected claims 16-18 are canceled herein.

### IV. Rejection Under 35 U.S.C. §102(b)

Claims 1-3, 10 and 11 are rejected under 35 U.S.C. §102(b) over EP '847. Applicants respectfully traverse this rejection.

Independent claim 1 is directed to a method for introducing a foreign matter into a cell, comprising the steps of: placing a small particle carrying a foreign matter at a part of a cell surface of a living cell, boring a hole in a cell wall and/or a cell membrane by irradiating and treating said part of the cell surface with a laser beam, and introducing the foreign matter into the living cell. Such a method is not disclosed in EP '847.

EP '847 discloses transducing a genetic substance into a microspore cell through a pore formed by a laser pulse thereby to express genetic information of the genetic substance.

EP '847 at Abstract. In Example 1, cited in the Office Action, EP '847 teaches a DNA solution composed of (i) Okada solution, (ii) 15% mannitol, (iii) 10 µg/ml of pBI221, (iv) 10 µg/ml of pSBG102 (Hm<sup>r</sup>), and (v) 50 µg/ml of Calf Thymus DNA. The solution is applied to a microspore cell and is laser processed. EP '847 at page 3, line 50 to page 4, line 15.

However, contrary to the position taken in the Office Action, EP '847 does not disclose the claimed "small particle carrying a foreign matter." EP '847 does not teach that the foreign matter is carried by a small particle. Instead, EP '847 merely discloses that the "foreign matter" (i.e., the plasmid pBI221) is in solution.

The Office Action takes the position that "the language 'a small particle carrying a foreign matter at a part of a cell surface of a living cell' is indefinite and is read broadly to mean an aqueous solution containing the 'foreign matter'" in EP '847. However, Applicants submit that the Office Action's position is incorrect and ignores the claim language.

First, the Office Action states that the cited claim language is "indefinite," but fails to reject the claim under 35 U.S.C. § 112, second paragraph. If the claim language is not indefinite under § 112, second paragraph, then the language cannot be so indefinite under § 102(b) to be ignored and broadly interpreted in the manner taken in the Office Action. In fact, Applicants submit that the claim language is not indefinite, as the claim language clearly sets forth that the small particle carries a foreign matter, and the combination of the small particle and the carried foreign matter is placed at a part of a cell surface of a living cell. One of ordinary skill in the art would readily understand and appreciate the meaning of this claim language. The claim language is thus not indefinite.

Second, the Office Action uses the assertion of indefiniteness as a means to ignore an express claim limitation. By arguing that the phrase is indefinite, the Office Action ignores the express requirement in claim 1 that the foreign matter be carried by "a small particle." A particle as a carrier is physically distinct from a solution, and one of ordinary skill in the art would not equate a solution and a carrier particle.

Because the claims are clear and definite, and require a carrier particle, this limitation must be disclosed in EP '847 in order for EP '847 to anticipate the claimed invention. However, as described above, EP '847 does not disclose such a carrier particle, and thus cannot anticipate the claimed invention.

For at least these reasons, claim 1 and claims 2-3, 10 and 11 dependent therefrom are not anticipated by EP '847. Reconsideration and withdrawal of the rejection are respectfully requested.

V. Rejection Under 35 U.S.C. §103(a)

A. EP '847 and Gad

Claims 1-5, 10-11 and 13-15 are rejected under 35 U.S.C. §103(a) over EP '847 in view of Gad. Applicants respectfully traverse this rejection.

Claim 1 is described above. Independent claim 13 is directed to a method for introducing a foreign matter into a living cell, comprising the steps of: irradiating a living cell with a laser beam, removing a part of a cell wall of the living cell, exposing a part of the cell membrane, placing, on the exposed cell membrane, a liposome including a foreign matter, fusing the exposed cell membrane with the liposome, and thereby introducing the

foreign matter into the living cell. Claims 1 and 13, and their dependent claims, would not have been obvious over the cited references.

As discussed above, EP '847 discloses transducing a genetic substance into a microspore cell through a pore formed by a laser pulse thereby to express genetic information of the genetic substance. EP '847 at Abstract. In Example 1, cited in the Office Action, EP '847 teaches a DNA solution composed of (i) Okada solution, (ii) 15% mannitol, (iii) 10 µg/ml of pBI221, (iv) 10 µg/ml of pSBG102 (Hm<sup>r</sup>), and (v) 50 µg/ml of Calf Thymus DNA. The solution is applied to a microspore cell and is laser processed. EP '847 at page 3, line 50 to page 4, line 15. Gad is cited as disclosing the use of small liposome particles. The Office Action asserts that it would have been obvious to utilize the small liposome particles of Gad in the process of EP '847.

The requirements for a prima facie case of obviousness are specified and described in MPEP §2143. According to MPEP §2143, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference. Second, there must be a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations. The references applied in the Office Action do not provide the necessary motivation for their combination, and fail to teach or suggest all the claim limitations.

First, none of the references teach or suggest the limitation of the claimed invention that the small particle carries a foreign matter. Instead, as described in detail above, EP '847 teaches that the foreign matter is simply placed into solution, and not carried by a small particle. Although Gad teaches the use of small liposome particles, Gad does not teach that

such particles can be employed as carriers of the foreign matter in methods including irradiating a living cell with a laser beam. Thus, the references fail to teach or suggest all of the claim limitations.

Second, the references are improperly combined in the Office Action, because neither reference provides any motivation for the asserted combination. For example, neither reference teaches or suggests why the small liposome particles of Gad could or should be incorporated into the plasmid solution of EP '847. EP '847 teaches that the plasmid solution provides the desired result of incorporating the plasmid into the cell. However, neither EP '847 nor Gad teach or suggest what effect would result if the plasmid were instead mixed with or attached to the small liposome particles of Gad. In the absence of any such teachings, one of ordinary skill in the art would not have been motivated to combine the references in the manner asserted in the Office Action.

Moreover, the reason, suggestion or motivation for combining the references "can not come from the applicant's invention itself." In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). That is, the motivation for combining the references can not be a product of hindsight reconstruction of the claimed invention based on applicant's own disclosure. Such a hindsight reconstruction has clearly been made in the present Office Action. The Office Action asserts that the claimed invention would have been obvious based on a hindsight selection of the claimed limitations, as evidenced by the contradictory teachings of the cited references, none of which would suggest to one skilled in the art that the teachings could be combined and then further modified to render the claimed invention. Such a combination is improper because the references, viewed by themselves and not in retrospect, must suggest the combination asserted

by the Office Action. In re Shaffer, 229 F.2d 476, 108 USPQ 326 (C.C.P.A. 1956); In re Stoll, 523 F.2d 1392, 187 USPQ 481 (C.C.P.A. 1975). Here the references do not provide any motivation for combining the divergent teachings. The only motivation for combining the cited references in the manner asserted in the Office Action derives from the disclosure of the present application, which is clearly improper.

For at least these reasons, the claimed invention would not have been obvious to one of ordinary skill in the art over EP '847 in view of Gad. Reconsideration and withdrawal of the rejection are respectfully requested.

B. EP '847, Gad and Weber

Claims 1-5 and 9-15 are rejected under 35 U.S.C. §103(a) over EP '847 in view of Gad and further in view of Weber. Applicants respectfully traverse this rejection.

Claims 1 and 13 are discussed above. EP '847 and Gad are also discussed above.

Weber is cited in the Office Action as disclosing different laser irradiating devices, and the use of a microinjector. However, regardless of the teachings of Weber, neither EP '847 nor Gad teach or suggest all of the limitations of the claimed invention, as described above. Weber fails to overcome the deficiencies of EP '847 and Gad, and fails to provide the necessary motivation for combining EP '847 and Gad in the manner asserted in the Office Action.

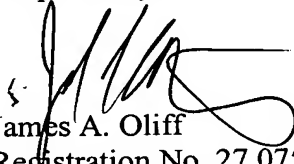
Accordingly, any combination of EP '847, Gad and Weber fails to have rendered obvious the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

VI. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

  
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JAO:JSA

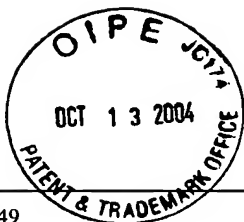
Attachment:  
April 25, 2002 Form PTO-1449

Date: October 13, 2004

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Sheet 1 of 1

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 111473		APPLICATION NO. 10/015,607	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Akio KOBAYASHI et al.			
				FILING DATE December 17, 2001		GROUP 1645	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		6,346,101	02/12/2002	Alfano et al.			
		4,945,050	07/31/1990	Sanford et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		JP B2 62-7837 (w/abstract)	02/19/1987	Japan			
		JP A 2-9378 (w/abstract)	01/12/1990	Japan			
		JP A 9-163984 (w/abstract)	06/24/1997	Japan			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		Kurata et al., "The Laser Method for Efficient Introduction of Foreign DNA into Cultured Cells", EXPERIMENTAL CELL RESEARCH 162 (1986) pp. 372-378.					
		Buer et al., "Insertion of Microscopic Objects through Plant Cell Walls Using Laser Microsurgery", BIOTECHNOLOGY AND BIOENGINEERING, vol. 60, no. 3, November 5, 1998.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: April 25, 2002